EXHIBIT 17

SAVINGS

$1 TRILLION OVER 10 YEARS

GENERIC DRUG SAVINGS IN THE U.S.

(FOURTH ANNUAL EDITION: 2012)

EXECUTIVE SUMMARY

One trillion dollars in health care savings over the past decade! A current rate of more than one billion dollars in savings every other day! The Generic Drug Savings study presents data and a retrospective analysis by the IMS Institute for Healthcare Informatics to quantify the unprecedented savings generated by market competition from generic pharmaceuticals. This study, published by the Generic Pharmaceutical Association (GPhA), validates the dramatic contribution the generic pharmaceutical industry makes every year to assuring the sustainability of the U.S. health care system.

The government's most recent National Health Expenditure Accounts (NHEA) report shows that total U.S. health care spending reached $2.6 trillion in 2010, which translates to $8,402 per person or about 18 percent of the nation's Gross Domestic Product (GDP).[1] The federal government financed 29 percent of the total spend—a substantial increase from its 23 percent share in 2007—with state and local governments paying an additional 16 percent of national health care costs.[2]

NHEA further notes that the average annual growth in health care spending is expected to be 6.2 percent per year through 2018, outpacing annual growth in the overall economy (anticipated at 4.1 percent) by 2.1 percentage points per year. By 2018, according to government projections, national health care spending will reach $4.4 trillion and comprise over one-fifth of the GDP.[3] At this rate of growth, within 15 years health care costs would amount to half of the nation's GDP, begging the question whether our yearly spending on health care is sustainable.

Against this backdrop of escalating costs, the Generic Drug Savings analysis shows conclusively that the use of lower cost generic prescription drugs is a vital component to holding down the growth rate of health care spending. As the study shows, generic drug use has saved the U.S. health care system approximately *$1.07 trillion* over the past decade (2002 through 2011) with $192.8 billion in savings achieved in 2011 alone. Considering that the government's share of health care spending will soon exceed 30 percent as the oldest baby boomers become eligible for Medicare, the money saved by using generic medicines is critical to bending the cost curve and providing sustainability to our health care system. Indeed, the NHEA report concluded that, while overall health care costs continue to grow at a rate higher than national economic growth, the growth in drug spending is slowing (only 1.2 percent in 2010), driven by "continued increase in the use of generic medications."[4]

As this fourth annual edition of the Generic Drug Savings study highlights, future savings achieved through generic prescription medicines will climb at an ever-increasing annual rate as generic versions of expensive branded biologic treatments begin entering the market. Current biologic medicine costs are staggering, putting these lifesaving treatments out of reach for many patients. Even after insurance coverage, co-pays can be thousands of dollars each year. A Congressional Research Service (CRS) study completed in 2010 showed that the cost of biologics is often prohibitively high, both for patients and the government. The report found that average annual costs for the rheumatoid arthritis treatment Enbrel® was $26,000, Herceptin® for breast cancer averaged $37,000, Humira® for Crohn's disease was more than $51,000 per year, and the annual cost for Cerezyme® to treat Gaucher's disease was $200,000. CRS noted further that Medicare spent

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1 Centers for Medicare and Medicaid Services (2012, April 11). *National Health Care Expenditure Data*. Retrieved June 1, 2012, from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/proj2010.pdf

2 *ibid*.

3 *ibid*.

4 *ibid*.

more in 2009 on just one biologic drug (Epogen®) than the entire FDA budget for that year, including all food, drug and cosmetic programs. CRS concluded that spending on biologics will be unsustainable without the approval of biosimilars to "enable market competition and reduction in prices."[5] Today, government spending for biologics is increasing at a faster pace than any other health care-related expense with the exception of diagnostic imaging tests. Last year, spending for biologics in the U.S. accounted for more than a quarter of the country's total drug bill.[6] Competition from biosimilar versions of branded biologics will help reign in these escalating costs and deliver sizeable savings while providing affordable options to patients needing treatments for deadly diseases.

All data in the 2012 Generic Drug Savings study were supplied by the IMS Institute for Healthcare Informatics, a division of IMS Health that, for more than 55 years, has been a leading provider of market intelligence to the health care industry. Other findings of this study show:

- The $192.8 billion saved in calendar year 2011 equates to a savings of more than *one billion dollars every other day.*
- 2011 savings from generics increased 22 percent over the prior year, marking the largest year-over-year increase since 1998, and 10 percentage points higher than the 10-year average.
- Savings from newer generic medicines—those that have entered the market since 2002—continue to increase exponentially, totaling $481 billion over the past 10 years.
- Generic versions of central nervous system (CNS) drugs, such as antidepressants and anticonvulsants, and cardiovascular drugs account for 57 percent of the annual savings.
- In 2011, nearly 80 percent of the 4 billion prescriptions written in the U.S. were dispensed using safe and effective generic versions of their brand name counterpart drugs.

This remarkable record of savings over the past decade dwarfs initial savings estimates made in 1984 when the Hatch/Waxman Act established the modern-day generic industry. At that time, it was projected that generics could save up to a billion dollars over the 10-year period following enactment of the bill. But a 1998 Congressional Budget Office study reported that, by the end of the first post-Hatch/Waxman decade, generics were saving between $8 billion and $10 billion *a year.*[7] Today, that amount is being saved every 18 days as consumers, patients, payers and federal, state and local governments increase their reliance on safe, effective and affordable generic medicines. The generic pharmaceutical industry continues to work for people around the globe by providing the safe and affordable medicines needed to live longer, healthier, and more productive lives.

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5 Johnson, J. A. (2010, April 26). *FDA Regulation of Follow-On Biologics.* Congressional Research Service; 7-5700:RL34045. www.crs.gov

6 Seeking Alpha (2012, March 6). Generic Competition: *The $100 Billion Biologics Arena.* Retrieved June 4, 2012, from http://seekingalpha.com/article/414781-generic-competition-the-100-billion-biologics-arena

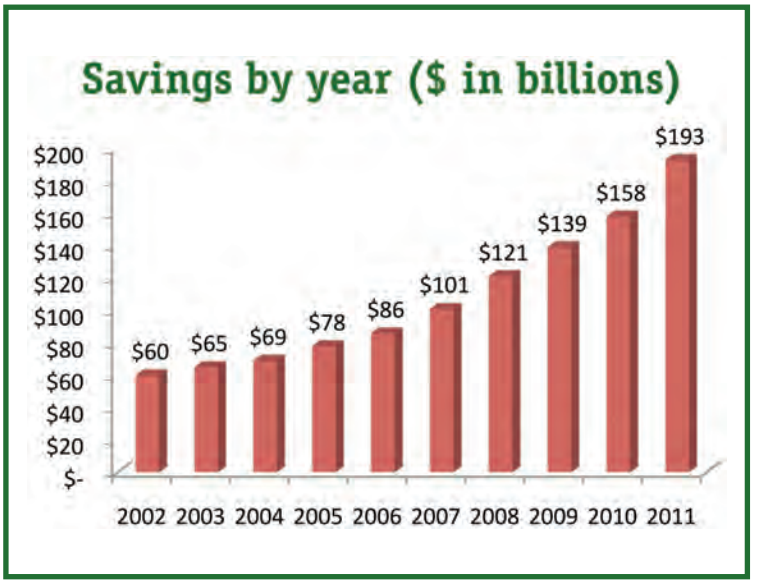
7 O'Neill, J. E., (July 1998). "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry." The U.S. Congress Congressional Budget Office. Available at www.cbo.gov

OVERVIEW

Spending on medicines in the U.S. reached $320 billion in 2011, as more than 4 billion new and renewal prescriptions were dispensed at pharmacies, in hospitals and long term care facilities, and through mail order services across the country. This record level of spending on pharmaceuticals would have been over 50 percent higher—totaling more than $500 billion—if not for the availability of lower cost generic versions of branded drugs.

Competition from Generics Has Driven Savings for the Past Decade

National spending data from 2011 show that the use of generic drugs saved American consumers, taxpayers, federal and state governments and other payers an astounding *$1.07 trillion* over the decade 2002 through 2011. In 2011 alone, the use of generics saved $193 billion, an average of more than *one billion dollars in savings every other day.* This represents a 20 percent increase in savings over 2010 savings of $158 billion, the largest one-year growth rate since 1998. This dramatic increase in savings was driven by the introduction of new generics for several significant brand drugs, including the billion dollar blockbusters Zyprexa® (olanzapine), Levaquin® (levofloxacin), Advair Diskus® (fluticasone propionate) Concerta® (methylphenidate) and Lipitor® (atorvastatin).



Across all drug products, first-time generics were launched in 2011 for brand drugs with $22.1 billion in annual sales. Because several of the new generics did not become available until late last year, the full benefit of generic cost reductions has not yet been realized. However, for the 5-year period ending 2011, the "patent dividend" (health care savings due to patent expiry and first-time generic competition) was $65.2 billion.[8]

Also accelerating the growth in generic savings is increasing consumer reliance on safe and effective generic drugs. The overall generic utilization rate reached 80 percent in 2011, meaning that more than 3.2 billion of the approximate 4 billion total brand and generic prescriptions written in the U.S. last year were dispensed using generic versions of branded drugs.

This overall generic utilization rate includes all prescription drugs, even those that are available only as brands. When looking only at the universe of drugs for which brand and generic versions are available, consumers chose the generic alternative 94 percent of the time in 2011. The overwhelming acceptance by consumers, patients and health care providers attests to the safety and sameness of FDA-approved generic drugs.

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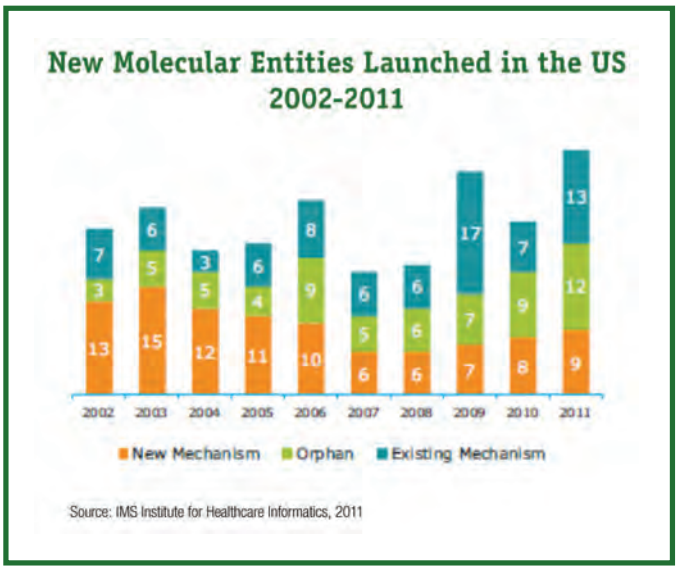
8 Kleinrock, M. (April 2012). *The Use of Medicines in the United States: Review of 2011.* IMS Institute for Healthcare Informatics: Parsippany, NJ.

Competition Did Not Slow the Innovation of New Medicines

The 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman) had the dual objectives of incentivizing the development of new brand drugs (the patent term restoration part) and facilitating the approval of generics to lower consumer costs (the drug price competition part). Some claim that Hatch-Waxman has worked too well for the generic side, at the cost of harming the innovation of new or improved medicines. An article in the November 2011 issue of *Health Affairs* argued that generic usage has increased so markedly that the incentive to develop new drugs has been harmed. The article called on Congress to review whether Hatch-Waxman is achieving its intended purpose of balancing incentives for generics and innovation with an eye toward amending the law to delay generic competition by increasing the market monopoly for branded drugs.[9]



But the facts do not support that claim. IMS reported in April that, although generic utilization has reached new levels, more new medicines were launched in 2011 than in any other year of the past decade. IMS noted, "New medicines launched last year brought improved efficacy, safety and convenience for diseases affecting millions of patients battling chronic conditions; important breakthroughs for rare diseases transformed treatment options through personalized medicines based on genetic markers for subtypes of cancer and individually cultured immunotherapies."[10]

In fact, since the implementation of Hatch-Waxman, there has been a multiple-fold increase in the innovation of new medicines, including the cholesterol drugs Lipitor® and Zocor®, the antidepressants Prozac® and Paxil®, the antipsychotic Zyprexa®, anti-ulcerants Prilosec® and Nexium®, and the blood thinner Plavix® to name a few. Each of these new treatments represents vast improvements in therapy that were spawned by competition to the older medicines. By creating a fair balance between innovation of new medicines and accessibility to lower cost generic medicines, federal law has established a win-win for providers and American consumers.

Competition from Biosimilars Will Add Tens of Billions of Dollars in New Savings

The proven track record of savings for consumers using traditional generic drugs can be duplicated in the biopharmaceutical market. The approval of biosimilars will inject the competition needed in the biologic market to lower costs and provide significant savings for patients in need of these lifesaving treatments. Estimates from various economic impact studies pin the projected savings from $42 billion on the low end to as high as $108 billion over the first 10 years of biosimilar

9 Grabowski, H. G., et al. (November 2011). "Evolving brand-name and generic drug competition may warrant a revision of the Hatch-Waxman Act." Health Affairs 30(11):2157-66.

10 Kleinrock, M. (April 2012). *The Use of Medicines in the United States: Review of 2011.* IMS Institute for Healthcare Informatics: Parsippany, NJ.

market formation. The Congressional Budget Office (CBO) has estimated that competition from biosimilars would yield "substantially lower prices" for lifesaving treatments. CBO estimates that biosimilars initially will be priced about 25 percent below their brand-name counterparts and, after several years of competition, would be priced as much as 40 percent below the brand. These savings will be invaluable as spending on biologics continues to soar. Whereas spending for traditional drugs grew 1.2 percent in 2011, spending for biologics grew more than 7 percent. And what is a $120 billion market in 2011 is projected to become a $200 billion market in 2015.[11]

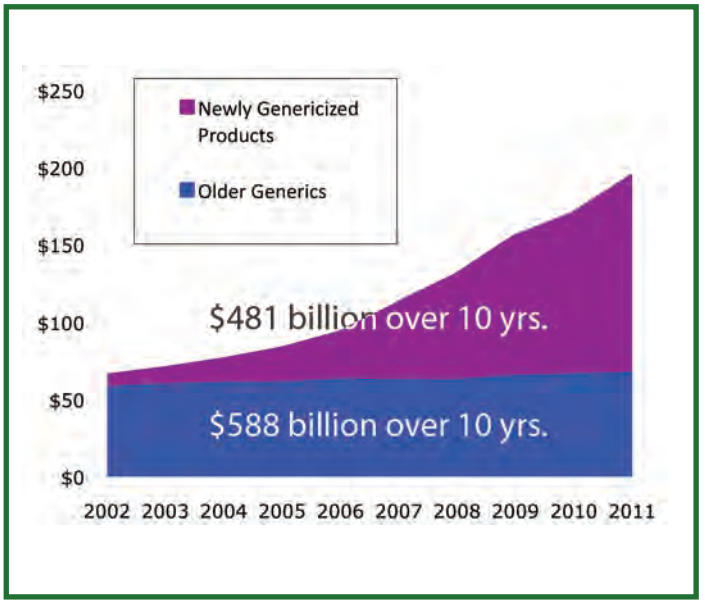
The only sure way to reign in costs is through the introduction of competition. It is essential that FDA maintains its commitment to funding the biosimilars program and ensures that a workable approval pathway is created…free from obstacles that would serve only to delay the availability of FDA-approved, safe, effective and lower-cost biosimilar treatments.

2011 SAVINGS ANALYSIS

Savings from newer generic medicines—those that have entered the market since 2002—continue to increase exponentially and account for more than one-third of the total savings. The IMS analysis found that the savings from generics introduced in the past 10 years has now reached approximately $481 billion and accounts for more than 40 percent of the overall generic savings. In 2011 alone, the U.S. health care system saved nearly $130 billion from these recently genericized drugs, or more than two-thirds of the savings for the entire year.

Older generic medicines, those drugs approved prior to 2002, continued to provide a foundation of cost reduction as well, yielding nearly $60 billion in savings in 2011.

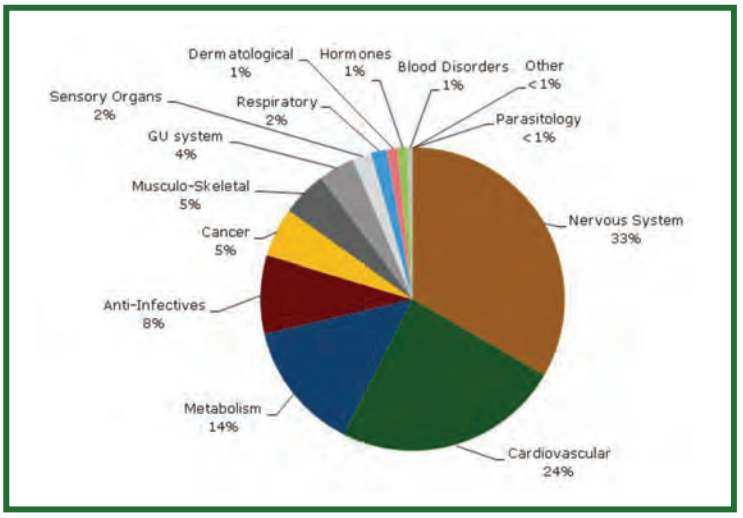
Savings from newer generics will increase over the next several years as many of the largest selling brand drugs lose patent protection and face generic competition for the first time. That includes blockbusters such as Aricept®, Singulair® and Actos®. Between 2012 and 2015, brand drugs with $67 billion in annual sales will lose patent protection. Patents also will expire for brand biologics with more than $25 billion in annual sales.[12] As a result, generic utilization will reach nearly 87 percent by 2015, IMS projects. These factors make it crystal clear that generic drugs are an integral part of the solution in reigning in U.S. health care costs.



11 IMS MIDAS, MAT December 2010. IMS Institute for Healthcare Informatics
12 *ibid.*

Central Nervous System, Cardiovascular and Metabolism Drugs Lead Savings

Generic central nervous system (CNS) and cardiovascular drugs delivered the bulk of the savings (approximately 57 percent) generated by the generic industry in 2011. Combined, generics in these two therapeutic areas alone provided consumers and the U.S. health care system more than $100 billion in total savings. Generic CNS medications have contributed significantly to the yearly increase in savings, growing 10 percent in 2011 over the prior year. Generic metabolism drugs also represented a major source of health care savings in 2011, reducing costs by nearly $27 billion. Since 2002, the savings generated by products in the metabolism drug class have grown an astounding 500 percent. When added to the savings provided by generic CNS and cardiovascular medicines, these three therapeutic categories account for nearly three-fourths of all savings generated by generic drugs in 2011.



By far the greatest one-year savings growth rate came in the cancer treatment category. Savings from generic oncology products topped $10 billion in 2011, more than three times higher than the $3 billion that generic cancer drugs saved in 2010. Larger savings primarily were driven by the introduction of generic versions of two aromatase inhibitors, Taxotere® (docetaxel) and Gemzar® (gemcitabin), for which the brand patents expired.

Therapeutic Category Generic Savings by Year ($ in billions)

TA	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Metabolism	5,032	6,042	6,644	7,554	9,058	12,040	15,257	18,114	22,015	26,656
Blood Disorders	347	391	457	593	769	833	841	784	869	1,008
Cardiovascular	13,704	15,423	16,557	17,252	18,429	24,500	32,722	37,327	41,111	46,563
Dermatological	999	1,130	1,195	1,339	1,425	1,527	1,577	1,223	1,466	2,301
GU system	4,126	3,463	3,000	2,881	2,757	2,724	2,940	3,108	4,871	7,445
Systemic Hormones	5,169	4,814	4,775	4,470	3,429	2,741	2,267	2,143	2,113	1,890
Anti-Infectives	4,807	4,664	5,265	7,310	9,356	11,034	12,596	14,101	12,972	16,058
Cancer	448	683	993	1,511	1,685	1,844	2,224	2,577	3,104	10,067
Musculo-Skeletal	3,279	3,581	3,882	4,452	5,051	5,682	6,353	7,972	8,621	9,307
Nervous System	19,706	22,102	23,749	27,428	30,653	35,480	40,955	49,082	56,922	64,290
Parasitology	5	6	6	10	13	19	20	20	16	17
Respiratory	1,574	1,763	1,815	2,078	2,372	2,301	2,642	2,238	2,318	3,180
Sensory Organs	573	564	593	657	662	651	637	829	1,372	3,949
Other	1	7	19	29	37	45	62	66	74	76
Annual Total	59,769	64,626	68,931	77,535	85,659	101,376	121,031	139,518	157,843	192,808
Over Time	114,766	179,392	248,323	325,858	411,517	512,893	633,924	773,442	**931,285**	**1,069,096**

CONCLUSIONS

1. Cost containment and sustainability of health care. The analysis clearly demonstrates that any effort to reduce health care costs—whether on Capitol Hill or in state legislatures—must recognize the billions of dollars in savings that can be achieved through the use of generic medicines. For more than 25 years, generic prescription drugs have allowed millions of Americans to get the medicine they need at an affordable cost. As new health care reform policies are implemented, the savings generated by generics will help make it possible to improve lives for less. As government leaders in Washington and across the country look for ways to cut health care costs, this new analysis details the remarkable savings achieved through the use of generic medications.

With policymakers being forced every day to make difficult choices pertaining to spending and deficits, it is imperative that the savings available through generic use be recognized. Policies that encourage generic dispensing and steer clear of unwarranted restrictions on generic use can bring even greater savings to U.S consumers, patients, health care providers and payers.

2. Patent Settlements. With more than a third of annual savings generated by generic medications coming from products that have entered the market since 2001, it would be misguided to enforce a ban on patent litigation settlements since most new generics get to market as the result of a settlement. In fact, 17 of the 22 first-time generics launched in 2011 were the result of patent settlements, including Zyprexa®, Solodyne®, Levaquin® and Lipitor®.[13] Over the past 10 years, patent settlements have enabled dozens of first-time generics to come to market many months and even years before patents on the counterpart brand drugs expired. Patent litigation settlements have never delayed the launch of the generic past the expiration of the brand patent. U.S. Courts repeatedly have ruled that patent settlements are pro-consumer and pro-competitive.

An independent study by RBC Capital Markets, *Analyzing Litigation Success Rates,* found that generic companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases. But when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases. While the settlement issue has engendered opposition from some who contend such generic-brand agreements are anticompetitive, the federal courts and Congress have repeatedly recognized that settlements can be desirable options in patent litigation. The record is clear: settlements allow generic drugs to come to market long before patents on the counterpart brands expire, resulting in billions of dollars in annual savings. Year after year, settlements have proven to be pro-consumer and pro-competitive. Over the past 10 years, patent settlements have resulted in billions of dollars in savings as dozens of first-time generics have come to market prior to patents expiring on the counterpart brand drugs.

3. Funding for FDA's Office of Generic Drugs. In addition to new generic drug user fees, which begin October 1, 2012, increasing congressional appropriations to the FDA's Office of Generic Drugs (OGD) is also an essential component in ensuring the savings potential from generic medications is fully realized. Currently, more than 2,000 generic drug applications are awaiting OGD action, with as many as 365 of those for first-time generic drugs, according to the FDA. Savings are being left on the table each day this backlog continues to grow, as consumers and the government are forced to pay brand drug prices for prescriptions that could be available in affordable generic versions. With generic manufacturers now poised to provide the FDA with hundreds of millions of dollars in new user fee funding, it is critical that members of Congress follow suit to ensure that the savings generated by the use of generic medications will continue to grow.

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13 Green, A. (2010, January 15). *Analyzing Litigation Success Rates.* Royal Bank of Canada Capital Markets.

METHODOLOGY

This analysis from the IMS Institute for Healthcare Informatics, a division of IMS Health, updates the third edition of the Generic Drugs Savings Study released in September 2011. This analysis is designed to show the total cost savings that generic pharmaceuticals provided to the U.S. health care system over the 10-year period of 2002 through 2011.

The fourth edition utilizes IMS data on sales and unit volumes of brand and generic products, estimating potential savings at the molecule level. To ensure consistency of the analysis, branded products are defined as originator molecules that no longer are patent protected; generic drugs are those that were introduced after the patent protection had expired on the original reference product. The total savings was derived from a universe of 2,750 drugs, which are those products for which both brands and generics were available on the market.

Types	% of Molecules
1. Brands without Generic Competition	25%
2. Loss of Exclusivity: after 2001	18%
3. Loss of Exclusivity: 2001 and before	12%
4. No Brand Volume in the Data Set	45%
Total Number	2750

Source: IMS Health, Midas, Dec 2011
Data Source includes: US Clinics, Drugstores, Federal Facilities, Food Stores, HMOs, Home Healthcare, Long Term Care, Mail Service, Non-Fed Hospital and Misc.

As shown in the chart at right, excluded from the savings analysis were drug products for which: (1) there was no measurable generic competition, either because of an exclusivity or patents still in effect or because there was no generic version of the brand yet approved; and (2) only a generic drug was available for sale because the brand drug was no longer available on the market. The overall methodology approach was to add 2011 generic volume to the 2010 Savings Study data for each molecule. The average brand price in the last year of patent protection (for patent expirations before 2001) was estimated using the formula (total brand sales) divided by (total standard units of brand).

For year 2011 brands under generic competition, the estimated value of the replaced brand product with generics was calculated using the formula (average brand price) multiplied by (total standard units of generic). Finally, the generic cost savings was computed using the formula (value of replaced brands with generics) minus the (total sales of generics), with total savings equal to the sum total of all cost savings across all therapeutic areas. To obtain the most accurate savings estimate, "standard units" are used throughout the study. The standard unit is the "number of units" divided by "smallest common dose of a product form." Number of units refers to the number of tablets or capsules, ml or grams sold, multiplied by the number of packages sold, then multiplied by package size.

For additional information on any of the topics discussed in this study, including Medicaid generic drug utilization, funding for the FDA's Office of Generic Drugs, patent settlements, biosimilars, and trends for the pharmaceutical industry, contact GPhA at 202-249-7100, or visit www.gphaonline.org. This IMS analysis was commissioned by the Generic Pharmaceutical Association; 777 6th Street, NW, Suite 510; Washington, DC 20001. It is available online at www.gphaonline.org.

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Q/ Which oral antibiotics are best for acne?

EVIDENCE-BASED ANSWER

A/ DOXYCYCLINE IS EFFECTIVE (strength of recommendation [SOR]: **B,** randomized controlled trial) and the antibiotic of choice (SOR: **C**, expert opinion) for moderate to severe inflammatory acne requiring oral treatment. Limiting side effects include photosensitivity and gastrointestinal (GI) disturbance.

Other members of the tetracycline family are considered second-line agents because of their side-effect profile and are contraindicated in pregnancy and for children younger than 12 years (SOR: **A**, meta-analysis, and **C**, expert opinion). For these patients, erythromycin is effective and better studied than azithromycin (SOR: **C**, expert opinion). Otherwise, emerging resistance and GI disturbances make erythromycin a third-line treatment.

The use of oral antibiotics should be limited to moderate to severe inflammatory acne unresponsive to topical therapies, including retinoids and antibiotics (SOR: **C**, expert opinion). Oral antibiotics should be used for at least 6 to 8 weeks and discontinued after 12 to 18 weeks of therapy (SOR: **C**, expert opinion).

Evidence summary

Acne vulgaris is an extremely common disorder affecting up to 95% of adolescents.[1] Doxycycline improves inflammatory lesions and has a tolerable side-effect profile.

Doxycycline: Fewer lesions, few side effects

A 2003 randomized, double-blind, controlled trial of 51 patients demonstrated that a subantimicrobial dose of doxycycline (20 mg orally twice a day) reduced comedonal lesions by 53.2% (from 31 to 16; P=.04) and inflammatory lesions by 50.1% (from 55 to 25; P<.01), whereas placebo decreased comedonal lesions by 10.6% (from 51 to 46; P=.4) and inflammatory lesions by 30.2% (from 27 to 19; P<.01).[2]

The most commonly reported adverse effects of doxycycline are GI disturbance and sensitivity to ultraviolet radiation (sunlight). A recent systematic review found an adverse event rate of 13 per 1 million prescriptions written.[3]

Minocycline: Probably effective, but not the first choice

A 2003 Cochrane review examined 27 randomized trials that compared oral minocycline with placebo or other active treatments, including topical and systemic antibiotics, in a total of 3031 patients with acne vulgaris on the face or upper trunk.[4] The review determined that minocycline is *probably* an effective treatment for moderate acne vulgaris. However, no reliable evidence from randomized controlled trials (RCTs) justifies its use as a first-line agent, especially given its higher cost relative to other treatments.

Drug resistance weakens macrolides' "punch"

Macrolide antibiotics, primarily erythromycin, were at one time considered first-line treatment for acne, but have fallen out of favor because of emerging drug resistance. Nevertheless, erythromycin's price and safety in pregnant women and young children has

TABLE 1

Estimated cost of oral acne medications

Medication	Dose, formulation, and frequency	Cost of 30-day supply*
Doxycycline hyclate	100 mg capsule daily	$12.99
Doxycycline hyclate	100 mg tablet daily	$20.99
Extended-release minocycline	45 mg tablet daily	$450.97
Minocycline	100 mg capsule twice a day	$45.98
Minocycline	100 mg tablet twice a day	$227.98
Erythromycin base	250 mg enteric-coated capsule 4 times a day	$154.62
Erythromycin base	250 mg tablet 4 times a day	$114.62
Azithromycin	500 mg tablet daily, 3 days/wk	$175.20

*http://www.drugstore.com. Accessed April 10, 2011.

TABLE 2

Safety and adverse-effect profiles of acne medications[8]

Medication	Adverse effects	Pregnancy category	Lactation safety	Appropriate age range
Doxycycline hyclate	Photosensitivity, GI disturbance, elevated BUN	D	Avoid	>12 y
Minocycline	Tooth discoloration, dizziness, hypersensitivity syndrome	D	Avoid; milk effects possible	>12 y
Erythromycin base	GI disturbance, nausea	B	Safe	FDA-approved for children
Azithromycin	Abdominal pain, GI disturbance	B	Minimal risk	Extended-release formula not FDA-approved for children

BUN, blood urea nitrogen; GI, gastrointestinal.

Doxycycline is the antibiotic of choice for moderate to severe inflammatory acne requiring oral treatment.

maintained its standing in acne therapy. A 1986 RCT that compared erythromycin with tetracycline found comparable efficacy: a 65% reduction in papules, from 21 to 12 lesions, for erythromycin and a 62% reduction, from 17 to 10 lesions, for tetracycline ($P<.0001$).[5] The main side effect of macrolide antibiotics is GI disturbance.

A 2006 RCT randomized 290 patients to the macrolide azithromycin (500 mg daily for 3 consecutive days a week in the first month, then 250 mg every other day for 2 months) or tetracycline (1 g daily for 1 month, then 500 mg daily for 2 months). The drugs produced comparable results: an 84.7% improvement with azithromycin and a 79.7% improvement with tetracycline ($P<.05$).[6] Compared with other macrolides and tetracycline , azithromycin has a more tolerable side-effect profile with fewer GI disturbances.

Lack of sufficient data on trimethoprim ± sulfamethoxazole, fluoroquinolones, and

cephalosporins precludes their inclusion in routine acne treatment.

Recommendations

The American Academy of Pediatrics (AAP) recommends topical retinoids as the foundation of treatment for most acne patients, and a topical microbial agent for additional therapy. Oral antibiotics should be reserved for moderate to severe inflammatory acne; tetracyclines are the standard first-line choice in most cases. The AAP warns against giving tetracyclines to children younger than 10 years because of the risk of permanent discoloration of teeth and abnormal skeletal development.[7,8]

The American Academy of Dermatology also recommends topical retinoids as first-line therapy for acne followed by oral doxycycline or minocycline if needed. Erythromycin is recommended for patients who can't use tetracyclines, but with a warning about possible bacterial resistance.[9]

TABLE 1 shows the cost of various acne medications. **TABLE 2** outlines their safety and risk profiles. JFP

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EXHIBIT 190

DORYX®
(doxycycline hyclate delayed-release tablets)
200 mg

Indication and Usage

DORYX® is an oral antibacterial drug available only by prescription that is used in combination with other medicines to treat severe acne. You should use DORYX® only as directed by your doctor to reduce the chance that bacteria will become resistant to this antibacterial drug and similar drugs. **Please read additional safety information below.**

PRESCRIBING INFORMATION | IMPORTANT SAFETY INFORMATION

DORYX® (doxycycline hyclate delayed-release tablets) is **the #1 Prescribed** Branded Doxycycline by Dermatologists

- Do you feel you have severe acne?
- Have you tried any of the following for your severe acne?
  - Non-prescription medications
  - Topical prescription medications
  - Oral prescription medications
- Are you interested in learning more about the #1 prescribed branded doxycycline for acne by dermatologists, DORYX® (doxycycline hyclate delayed-release tablets, USP), to help treat your severe acne?
  - DORYX® is an oral antibacterial drug available only by prescription that is used in combination with other medicines to treat severe acne
  - You should use DORYX® only as directed by your doctor to reduce the chance that bacteria will become resistant to this antibacterial drug and similar drugs
  - The usual dose of DORYX® is 200 mg on the first day of treatment taken as 100 mg every 12 hours, followed by a maintenance dose of 100 mg once-daily. However, you should take DORYX® exactly as directed by your healthcare provider

Make a Break From Severe Acne

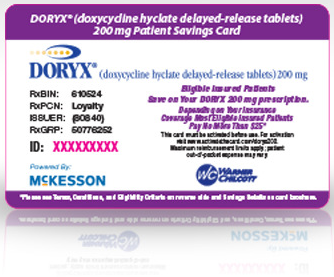
- *Ask your Dermatologist if you have severe acne*
- *Ask your Dermatologist if DORYX® (doxycycline hyclate delayed-release tablets) 200 mg is right for you*
- *If DORYX® 200 mg has been prescribed, ask your Dermatologist for a free DORYX® 200 mg sample and a savings card* with your prescription*

*Eligible insured patients only. Please see Patient Savings Card for Terms, Conditions, and Eligibility Criteria.

Eligible insured patients click here to activate your Patient Savings Card

See program terms, conditions and eligibility criteria on back of card and savings details on card brochure. Maximum reimbursement limits apply.

If you have any questions about the Patient Savings Card, call us at: 1-877-512-4250 (8:00 am-8:00 pm EST, Monday-Friday)



Important Safety Information about DORYX® (doxycycline hyclate delayed-release tablets)

Do not take DORYX® if you are allergic to tetracyclines. Like other tetracyclines, doxycycline can harm an unborn child when taken by a pregnant woman. Talk to your doctor if you are pregnant or are breastfeeding. DORYX® should not be used when a childâ€™s teeth are forming (during the last half of pregnancy and up to the age of 8 years) because it may cause permanent darkening of teeth. Oral contraceptives may not work as well when you are taking DORYX®.

Diarrhea may occur with the use of antibacterial drugs and may range from mild to severe. If you develop watery and bloody stools (with or without stomach cramps or fever) even as late as two or more months after having taken the last dose of DORYX®, please call your doctor as soon as possible.

Sensitivity to natural or artificial sunlight can occur with tetracycline-class drugs. Avoid excessive sunlight and consider using sunscreen or sunblock. Stop taking DORYX® and call your doctor if you develop a severe sunburn.

The most common side effects seen in patients taking tetracyclines include anorexia, nausea, vomiting, diarrhea, rash, sensitivity to sunlight, hives, and low red blood cell count (anemia).

For additional safety and other information, please see Full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Doryx® is a registered trademark of Warner Chilcott Company, LLC.